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Of Counsel for Plaintiffs Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HORIZON PHARMA IRELAND LIMITED, HZNP LIMITED and HORIZON PHARMA USA, INC.,

Plaintiffs,

v.

ACTAVIS LABORATORIES UT, INC.,

Defendant.

CIVIL ACTION No. 1:16-cv-05051

Document Filed Electronically

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

AMENDED COMPLAINT

Plaintiffs Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc. (collectively, "Plaintiffs"), by their undersigned attorneys, bring this action against Defendant Actavis Laboratories UT, Inc. ("Defendant" or "Actavis UT"), and hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, arising from Defendant's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug

Administration ("FDA") seeking approval to market a generic version of Plaintiffs' pharmaceutical product PENNSAID® (diclofenac sodium topical solution) 2% w/w ("PENNSAID® 2%") prior to the expiration of United States Patent Nos. 9,339,551 ("the '551 patent"), 9,339,552 ("the '552 patent"), 9,375,412 ("the '412 patent"), and 9,370,501 ("the '501 patent"), which cover PENNSAID® 2% and its use.

THE PARTIES

2. Plaintiff Horizon Pharma Ireland Limited is a corporation organized and existing under the laws of Ireland, with a principal place of business at Adelaide Chambers, Peter Street, Dublin 8, Ireland.

3. Plaintiff HZNP Limited is a nonresident Irish company that is a tax resident of Bermuda, with a principal place of business at 21 Laffan St., Hamilton, Pembroke, Bermuda HM09.

4. Plaintiff Horizon Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 150 S. Saunders Rd, Lake Forest, Illinois.

5. On information and belief, Defendant Actavis UT is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 577 Chipeta Way, Salt Lake City, Utah.

6. On information and belief, Actavis UT was formerly known as Watson Laboratories, Inc. This change of name was effective in or about January 2015.

7. On information and belief, Actavis UT is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within this judicial district, through its own actions.

8. On information and belief, Defendant participated and collaborated in the research and development, and the preparation and filing, of Actavis UT's ANDA No. 207238 ("the Actavis UT ANDA") for diclofenac sodium topical solution 2% w/w ("the

Actavis UT Product"), continues to participate and collaborate in seeking FDA approval of that application, and intends to participate and collaborate in the commercial manufacture, marketing, offer for sale and sale of the Actavis UT Product throughout the United States, including in the State of New Jersey, in the event the FDA approves Actavis UT's ANDA.

9. On information and belief, Actavis UT (under its former name, Watson Laboratories, Inc.) has not contested, or has otherwise submitted to, the jurisdiction of this Court in at least 14 prior District of New Jersey actions: *Horizon Pharma Ireland Ltd. et al. v. Actavis Labs. UT, Inc.*, Civil Action No. 14-cv-7992(NLH)(AMD); *Supernus Pharms., Inc. v. Actavis, Inc. et al.*, Civil Action No. 14-6102; *Supernus Pharms., Inc. v. Actavis, Inc. et al.*, Civil Action No. 14-1981; *Supernus Pharms., Inc. v. Actavis, Inc. et al.*, Civil Action No. 13-4740; *Auxilium Pharms., Inc. et al. v. Watson Labs., Inc., et al.*, Civil Action No. 12-3084; *Warner Chilcott Co. v. Watson Labs., Inc.*, Civil Action No. 12-2928; *Janssen Pharms., Inc, et al. v. Watson Labs., Inc., et al.*, Civil Action No. 08-5103; *Duramed Pharms. v. Watson Pharma, Inc, et al.*, Civil Action No. 07-5941; *Hoffman La-Roche Inc, et al. v. Cobalt Pharms. Inc., et al.*, Civil Action No. 07-4539; *Sanofi-Aventis et al. v. Watson Pharms., Inc., et al.*, Civil Action No. 07-443; *Warner Chilcott Co. v. Watson Pharms., Inc., et al.*, Civil Action No. 07-4697; *Novartis Corp. et al. v. Watson Labs., Inc., et al.*, Civil Action No. 06-1130; *Schering Corp. v. Zydus Pharms., USA, Inc., et al.*, Civil Action No. 06-4715; *Warner Chilcott Co. v. Watson Pharms., Inc., et al.*, Civil Action No. 06-3491.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

11. This Court has personal jurisdiction over Defendant by virtue of, *inter alia*, its presence in New Jersey, having conducted business in New Jersey, having availed itself of the rights and benefits of New Jersey law such that it should reasonably anticipate being haled into court in this judicial district, previously submitting to personal jurisdiction in this Court, availing itself of the jurisdiction of this Court (*e.g.*, by the

assertion of counterclaims), and having engaged in systematic and continuous contacts with the State of New Jersey through the marketing and sales of generic drugs throughout the United States, and in particular within this judicial district, through the receipt of revenue from the sales and marketing of generic drug products, including Actavis UT products, within this judicial district, and through its intent to market and sell the Actavis UT Product, if approved, to residents of this judicial district.

12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PATENTS-IN-SUIT

13. On May 17, 2016, the U.S. Patent and Trademark Office ("USPTO") duly and legally issued the '551 patent entitled "Diclofenac Topical Formulation."

14. HZNP Limited is the sole assignee and owner of all right, title and interest in and to the '551 patent, which discloses and claims, *inter alia*, methods for treating pain in a knee due to osteoarthritis by administering the topical formulation to the knee twice daily. A true and correct copy of the '551 patent is attached hereto as Exhibit A.

15. On May 17, 2016, the USPTO duly and legally issued the '552 patent entitled "Diclofenac Topical Formulation."

16. HZNP Limited is the sole assignee and owner of all right, title and interest in and to the '552 patent, which discloses and claims, *inter alia*, topical formulations and methods for treating pain in a knee due to osteoarthritis by administering the topical formulation to the knee twice daily. A true and correct copy of the '552 patent is attached hereto as Exhibit B.

17. On June, 28 2016, the USPTO duly and legally issued the '412 patent entitled "Treatment of Pain with Topical Diclofenac."

18. HZNP Limited is the sole assignee and owner of all right, title and interest in and to the '412 patent, which discloses and claims, *inter alia*, a method for applying

topical agents to a knee of a patient in pain. A true and correct copy of the '412 patent is attached hereto as Exhibit C.

19. On June 21, 2016, the USPTO duly and legally issued the '501 patent entitled "Treatment of Pain with Topical Diclofenac."

20. HZNP Limited is the sole assignee and owner of all right, title and interest in and to the '501 patent, which discloses and claims, *inter alia*, a method for applying topical agents to a knee of a patient in pain. A true and correct copy of the '501 patent is attached hereto as Exhibit D.

PENNSAID® 2%

21. Horizon Pharma Ireland Limited is the owner of FDA-approved New Drug Application No. 204623 ("the PENNSAID® 2% NDA") for diclofenac sodium topical solution 2% w/w (PENNSAID® 2%), which is sold in the US under the trade name PENNSAID®, and which is sold by Horizon Pharma USA, Inc.

22. The PENNSAID® 2% solution is currently approved by the FDA for the relief of pain of osteoarthritis of the knees.

23. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '551, '552, '412 and '501 patent are currently listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") for the PENNSAID® 2% NDA.

24. The '551, '552, '412 and '501 patents cover PENNSAID® 2% and FDA-approved uses.

ACTAVIS UT'S ANDA

25. On information and belief, Actavis UT submitted the Actavis UT ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market diclofenac sodium topical solution 2% w/w. On information and belief, the Actavis UT ANDA

seeks approval to market the Actavis UT Product for the relief of pain of osteoarthritis of the knees.

26. On information and belief, the Actavis UT ANDA refers to and relies upon the PENNSAID® 2% NDA and contains data that, according to Actavis UT, demonstrate the bioequivalence of the Actavis UT Product and PENNSAID® 2%.

27. HZNP Limited received from Actavis UT a letter, dated July 1, 2016 (the "Actavis UT Notification"), stating that Actavis UT had included a certification in the Actavis UT ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, the '551 and '552 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the Actavis UT Product (the "Paragraph IV Certification").

28. The Actavis UT Notification states that the Actavis UT ANDA seeks approval to engage in the commercial manufacture, use or sale of diclofenac sodium topical solution 2% before the expiration of the '551 and '552 patents.

29. The '412 and '501 patents were not addressed in the Actavis UT Notification.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 9,339,551

30. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-29 of this Complaint.

31. The '551 patent issued on May 17, 2016, and will expire no earlier than October 17, 2027.

32. By submitting and seeking approval of the Actavis UT ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or importation of the Actavis UT Product, prior to date on which the '551 patent expires, Defendant has infringed the '551 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

33. Defendant's commercial manufacture, use, offer to sell, or sale of the Actavis UT Product within the United States, or importation of the Actavis UT Product into the United States, during the term of the '551 patent, also would infringe the '551 patent under 35 U.S.C. § 271(a), (b) and/or (c).

34. Upon approval of the Actavis UT ANDA, and commercialization of the Actavis UT Product, Defendant will actively induce and/or contribute to infringement of the '551 patent.

35. Upon information and belief, Defendant had actual and constructive notice of the '551 patent as of its issue date, and Defendant's infringement of the '551 patent is willful.

36. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Actavis UT's ANDA be a date that is not earlier than the expiration of the '551 patent, or any later expiration of any exclusivity or extension of the '551 patent to which Plaintiffs or the patent may become entitled.

37. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to the infringement of the '551 patent.

38. Plaintiffs have no adequate remedy at law.

39. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT II FOR INFRINGEMENT OF U.S. PATENT NO. 9,339,552

40. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-39 of this Complaint.

41. The '552 patent issued on May 17, 2016, and will expire no earlier than October 17, 2027.

42. By submitting and seeking approval of the Actavis UT ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale of importation of the Actavis UT Product, prior to date on which the '552 patent expires, Defendant has infringed the '552 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

43. Defendant's commercial manufacture, use, offer to sell, or sale of the Actavis UT Product within the United States, or importation of the Actavis UT Product into the United States, during the term of the '552 patent, also would infringe the '552 patent under 35 U.S.C. § 271(a), (b) and/or (c).

44. Upon approval of the Actavis UT ANDA, and commercialization of the Actavis UT Product, Defendant will actively induce and/or contribute to infringement of the '552 patent.

45. Upon information and belief, Defendant had actual and constructive notice of the '552 patent as of its issue date, and Defendant's infringement of the '552 patent is willful.

46. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Actavis UT's ANDA be a date that is not earlier than the expiration of the '552 patent, or any later expiration of any exclusivity or extension of the '552 patent to which Plaintiffs or the patent may become entitled.

47. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to the infringement of the '552 patent.

48. Plaintiffs have no adequate remedy at law.

49. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT III FOR INFRINGEMENT OF U.S. PATENT NO. 9,375,412

50. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-49 of this Complaint.

51. The '412 patent issued on June 28, 2016, and will expire no earlier than July 10, 2029.

52. Defendant has previously filed certifications in the Actavis UT ANDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to market the Actavis UT Product prior to the expiration of, *inter alia*, the '551 patent, which expires on October 17, 2027. Because the '412 patent expires no earlier than July 10, 2029, Defendant seeks approval of the Actavis UT ANDA, and to market the Actavis UT Product, prior to the expiration of the '412 patent.

53. By submitting and seeking approval of the Actavis UT ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale of importation of the Actavis UT Product, prior to date on which the '412 patent expires, Defendant has infringed the '412 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

54. Defendant's commercial manufacture, use, offer to sell, or sale of the Actavis UT Product within the United States, or importation of the Actavis UT Product into the United States, during the term of the '412 patent, also would infringe the '412 patent under 35 U.S.C. § 271(a), (b) and/or (c).

55. Upon approval of the Actavis UT ANDA, and commercialization of the Actavis UT Product, Defendant will actively induce and/or contribute to infringement of the '412 patent.

56. Upon information and belief, Defendant had actual and constructive notice of the '412 patent as of its issue date, and Defendant's infringement of the '412 patent is willful.

57. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Actavis UT's

ANDA be a date that is not earlier than the expiration of the '412 patent, or any later expiration of any exclusivity or extension of the '412 patent to which Plaintiffs or the patent may become entitled.

58. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to the infringement of the '412 patent.

59. Plaintiffs have no adequate remedy at law.

60. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT IV FOR INFRINGEMENT OF U.S. PATENT NO. 9,370,501

61. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-60 of this Complaint.

62. The '501 patent issued on June 21, 2016, and will expire no earlier than July 10, 2029.

63. Defendant has previously filed certifications in the Actavis UT ANDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to market the Actavis UT Product prior to the expiration of, *inter alia*, the '551 patent, which expires on October 17, 2027. Because the '501 patent expires no earlier than July 10, 2029, Defendant seeks approval of the Actavis UT ANDA, and to market the Actavis UT Product, prior to the expiration of the '501 patent.

64. By submitting and seeking approval of the Actavis UT ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale of importation of the Actavis UT Product, prior to date on which the '501 patent expires, Defendant has infringed the '501 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

65. Defendant's commercial manufacture, use, offer to sell, or sale of the Actavis UT Product within the United States, or importation of the Actavis UT Product

into the United States, during the term of the '501 patent, also would infringe the '501 patent under 35 U.S.C. § 271(a), (b) and/or (c).

66. Upon approval of the Actavis UT ANDA, and commercialization of the Actavis UT Product, Defendant will actively induce and/or contribute to infringement of the '501 patent.

67. Upon information and belief, Defendant had actual and constructive notice of the '501 patent as of its issue date, and Defendant's infringement of the '501 patent is willful.

68. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Actavis UT's ANDA be a date that is not earlier than the expiration of the '501 patent, or any later expiration of any exclusivity or extension of the '501 patent to which Plaintiffs or the patent may become entitled.

69. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to the infringement of the '501 patent.

70. Plaintiffs have no adequate remedy at law.

71. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT V FOR DECLARATION OF INFRINGEMENT OF U.S. PATENT NO. 9,339,551

72. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-71 of this Complaint.

73. This count arises under the Declaratory Judgement Act, 28 U.S.C. §§ 2201 and 2202.

74. There currently exists an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

75. Defendant's commercial manufacture, use, offer to sell, or sale of the Actavis UT Product within the United States, or importation of the Actavis UT Product into the United States, during the term of the '551 patent, would infringe the '551 patent.

76. Defendant seeks approval of the Actavis UT ANDA, and to market the Actavis UT Product, prior to the expiration of the '551 patent.

77. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import the Actavis UT Product prior to the expiration of the '551 patent.

78. Plaintiffs are entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale and/or importation of the Actavis UT Product prior to the expiration of the '551 patent by Defendant would constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '551 patent.

79. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to the infringement of the '551 patent.

80. Plaintiffs have no adequate remedy at law.

81. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT VI FOR DECLARATION OF INFRINGEMENT OF U.S. PATENT NO. 9,339,552

82. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-81 of this Complaint.

83. This count arises under the Declaratory Judgement Act, 28 U.S.C. §§ 2201 and 2202.

84. There currently exists an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

85. Defendant's commercial manufacture, use, offer to sell, or sale of the Actavis UT Product within the United States, or importation of the Actavis UT Product into the United States, during the term of the '552 patent, would infringe the '552 patent.

86. Defendant seeks approval of the Actavis UT ANDA, and to market the Actavis UT Product, prior to the expiration of the '552 patent.

87. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import the Actavis UT Product prior to the expiration of the '552 patent.

88. Plaintiffs are entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale and/or importation of the Actavis UT Product prior to the expiration of the '552 patent by Defendant would constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '552 patent.

89. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to the infringement of the '552 patent.

90. Plaintiffs have no adequate remedy at law.

91. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT VII FOR DECLARATION OF INFRINGEMENT OF U.S. PATENT NO. 9,375,412

92. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-91 of this Complaint.

93. This count arises under the Declaratory Judgement Act, 28 U.S.C. §§ 2201 and 2202.

94. There currently exists an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

95. Defendant's commercial manufacture, use, offer to sell, or sale of the Actavis UT Product within the United States, or importation of the Actavis UT Product into the United States, during the term of the '412 patent, would infringe the '412 patent.

96. Defendant seeks approval of the Actavis UT ANDA, and to market the Actavis UT Product, prior to the expiration of the '412 patent.

97. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import the Actavis UT Product prior to the expiration of the '412 patent.

98. Plaintiffs are entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale and/or importation of the Actavis UT Product prior to the expiration of the '412 patent by Defendant would constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '412 patent.

99. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to the infringement of the '412 patent.

100. Plaintiffs have no adequate remedy at law.

101. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT VIII FOR DECLARATION OF INFRINGEMENT OF U.S. PATENT NO. 9,370,501

102. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-101 of this Complaint.

103. This count arises under the Declaratory Judgement Act, 28 U.S.C. §§ 2201 and 2202.

104. There currently exists an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

105. Defendant's commercial manufacture, use, offer to sell, or sale of the Actavis UT Product within the United States, or importation of the Actavis UT Product into the United States, during the term of the '501 patent, would infringe the '501 patent.

106. Defendant seeks approval of the Actavis UT ANDA, and to market the Actavis UT Product, prior to the expiration of the '501 patent.

107. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import the Actavis UT Product prior to the expiration of the '501 patent.

108. Plaintiffs are entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale and/or importation of the Actavis UT Product prior to the expiration of the '501 patent by Defendant would constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '501 patent.

109. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to the infringement of the '501 patent.

110. Plaintiffs have no adequate remedy at law.

111. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Defendant, and respectfully request the following relief:

A. A judgment declaring that Defendant has infringed and will infringe one or more claims of U.S. Patent No. 9,339,551;

B. A judgment declaring the Defendant has infringed and will infringe one or more claims of U.S. Patent No. 9,339,552;

C. A judgment declaring the Defendant has infringed and will infringe one or more claims of U.S. Patent No. 9,375,412;

D. A judgment declaring the Defendant has infringed and will infringe one or more claims of U.S. Patent No. 9,370,501;

E. A declaration pursuant to 28 U.S.C. § 2201 that if Defendant, its officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and their successors and assigns, manufacture, use, offer to sell, or sell the Actavis UT Product within the United States, or import the Actavis UT Product into the United States, prior to the expiration date of the '551 patent, it will constitute an act of infringement of the '551 patent;

F. A declaration pursuant to 28 U.S.C. § 2201 that if Defendant, its officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and their successors and assigns, manufacture, use, offer to sell, or sell the Actavis UT Product within the United States, or import the Actavis UT Product into the United States, prior to the expiration date of the '552 patent, it will constitute an act of infringement of the '552 patent;

G. A declaration pursuant to 28 U.S.C. § 2201 that if Defendant, its officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers,

distributors, suppliers, and those persons in active concert or participation with any of them, and their successors and assigns, manufacture, use, offer to sell, or sell the Actavis UT Product within the United States, or import the Actavis UT Product into the United States, prior to the expiration date of the ’412 patent, it will constitute an act of infringement of the ’412 patent;

H. A declaration pursuant to 28 U.S.C. § 2201 that if Defendant, its officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and their successors and assigns, manufacture, use, offer to sell, or sell the Actavis UT Product within the United States, or import the Actavis UT Product into the United States, prior to the expiration date of the ’501 patent, it will constitute an act of infringement of the ’501 patent;

I. If Defendant commercially manufactures, uses, offers to sell, or sells the Actavis UT Product within the United States, or imports the Actavis UT Product into the United States, prior to the expiration of the ’551 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

J. If Defendant commercially manufactures, uses, offers to sell, or sells the Actavis UT Product within the United States, or imports the Actavis UT Product into the United States, prior to the expiration of the ’552 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

K. If Defendant commercially manufactures, uses, offers to sell, or sells the Actavis UT Product within the United States, or imports the Actavis UT Product into the United States, prior to the expiration of the ’412 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

L. If Defendant commercially manufactures, uses, offers to sell, or sells the Actavis UT Product within the United States, or imports the Actavis UT Product into the United States, prior to the expiration of the ’501 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

M. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Actavis UT ANDA shall be a date not earlier than the expiration date of the ’551 patent, inclusive of any extensions;

N. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Actavis UT ANDA shall be a date not earlier than the expiration date of the '552 patent, inclusive of any extensions;

O. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Actavis UT ANDA shall be a date not earlier than the expiration date of the '412 patent, inclusive of any extensions;

P. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Actavis UT ANDA shall be a date not earlier than the expiration date of the '501 patent, inclusive of any extensions;

Q. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

R. Costs and expenses in this action; and

S. Such other and further relief as the Court deems just and proper.

Date: October 26, 2016

s/ John E. Flaherty
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Of Counsel for Plaintiffs Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc.

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc., by their undersigned attorneys, hereby certify pursuant to Local Civil Rule 11.2 that the matter in controversy is the subject of the following pending actions:

- *Horizon Pharma Ireland Limited, et al. v. Actavis Laboratories UT, Inc.*, Civil Action No. 14-cv-07992-NLH-AMD (D.N.J.) (Civil Action Nos. 1:15-cv-5025, -6131, and -6989, are consolidated for all purposes with this action);
- *Horizon Pharma Ireland Limited, et al. v. Actavis Laboratories UT, Inc.*, Civil Action No. 1:15-cv-07742-NLH-AMD (D.N.J.);
- *Horizon Pharma Ireland Limited, et al. v. Actavis Laboratories UT, Inc.*, Civil Action No. 1:16-cv-00645-NLH-AMD (D.N.J.); and
- *Horizon Pharma Ireland Limited, et al. v. Lupin Limited, et al.*, Civil Action No. 15-cv-03051-NLH-AMD (D.N.J.) (The schedules for Civil Action Nos. 1:15-cv-5027, -6935, -7745 and 1:16-cv-00732 are coordinated with this action).

October 26, 2016

s/ John E. Flaherty

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that true copies of the foregoing AMENDED COMPLAINT FOR PATENT INFRINGEMENT were caused to be served on October 26, 2016 via email and/or the ECF system upon all counsel of record.

By: *s/John E. Flaherty*
John E. Flaherty